

REMARKS

Claim 14-19 and 29-31 are pending in the present application, including independent claim 14. To better understand what is required by the present claims, reference is made to Figs. 4-5 of the specification (portions of which are reproduced below), which illustrate one embodiment of the present claims.

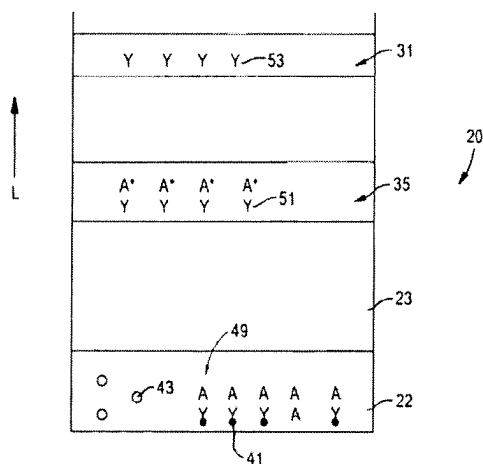


FIG. 4

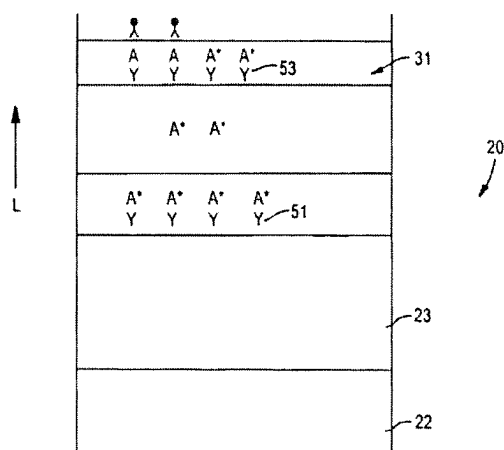


FIG. 5

As shown in Fig. 4, a test sample containing an antigen A travels in the direction “L” and mixes with fluorescent detection probes 41 conjugated with an antibody. The antigen A binds with the probes 41 to form analyte/conjugated probe complexes 49. Some of the antigen A remains free due to the limited availability of the probes 41. As shown in Fig. 5, the free antigen A and the complexes 49 then travel to the competitive zone 35, within which is immobilized an antibody 51 complexed to a labeled molecule A* that is identical in nature or an analog of the antigen A. Due to its smaller size, the free antigen A reaches the competitive zone 35 first, and competes with the molecule A* for the binding sites on the antibody 51. The complexes 49 and the displaced molecules A* travel on to the detection zone 31 and bind to an antibody 53. Once captured, the fluorescence signals of the labeled molecules A* and detection probes 41 may be measured at the detection zone 31 and the competitive zone 35.

In the Office Action, independent claim 14 was rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 7,144,742 to Boehringer, et al. in view of U.S. Patent No. 5,573,921 to Behnke, et al. An illustrative embodiment of the lateral flow device of Boehringer, et al. is shown in Fig. 1.

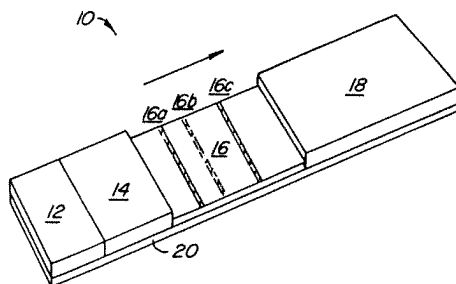


FIG. 1.

As shown, the device 10 contains a labeling zone 14, barrier zone 16a, and detection zones 16b and 16c. The labeling zone 14 has a biotinylated anti-analyte mouse IgG antibody, the *barrier zone 16a contains an analyte or analyte analogue*, and the detection zones contains antibodies or streptavidin of different affinities. As sample analyte concentration increases, a greater amount of the antibody from the labeling zone ("first sbp member") will form complexes with the sample analyte and thus pass through the barrier zone and become captured in the detection zones. The Office Action likened this "barrier zone" to the "competitive zone" of independent claim 14. Although the barrier zone does contain an analyte or an analyte analog, the competitive zone of independent claim 14 also contains "a second antibody" and requires that the "antigen" is "complexed" thereto. Furthermore, the antigen within the competitive zone contains "an optically detectable substance prior to the application of a test sample." None of these features are possessed by the barrier zone of Boehringer, et al.

Behnke, et al. was nevertheless cited in the Office Action as teaching an antibody complexed to an antigen. Referring to Fig. 1a of Behnke, et al., the test strip 1 includes antibody molecules 3 in a measurement area 2 and a tracer 4 that contains the analyte 5 and an appendage 6 (e.g., biotin) bound to the antibody molecules 3. When dipped into a test solution (Fig. 1b) containing the analyte 5 and reaction partner 9 (e.g., streptavidin-enzyme conjugate), each molecule of the analyte 5 can displace one tracer molecule 4. The displaced tracer 4 binds to the reaction partner 9 and migrates into an area 11 of the test strip located above the measurement area 2. The test strip 1 is then dipped into another vessel 12 containing a developing solution 13 (Fig. 1c). The

solution 13 contains substrate molecules 14 that enter the test strip 1 and react to form a dye 17.

As indicated above, Behnke, et al. does generally describe an antibody bound to an analyte analog (tracer). On this basis, the Office Action argues that it would have been obvious to combine this aspect with Boehringer, et al. because Behnke, et al. teaches the benefit of binding an analyte analog attached to a dye to an immobilized antibody so that "the bound analyte analog attached to the dye allows for directly visualizing the area of the test strip comprising the immobilized antibody (i.e., barrier zone) even before beginning the test." This rationale for combining the references, however, is contrary to the teachings of the references.

The purpose of Boehringer, et al., as explained above, is to include a "barrier zone" that exhibits a signal when the analyte concentration is either high or low and a "detection zone" for quantization of the analyte. If Boehringer, et al. were modified include an antibody/antigen complex at the "barrier zone", it would completely fail to fulfill its intended function because it would no longer be able to bind to the labeled binding member ("first sbp member"). The recent Office Action responds to this argument as follows:

Boehringer et al. . . . teaches. . . a barrier (competitive zone 16a that contains a second antibody immobilized on said porous membrane that can be complexed to an antigen containing a label . . . and allows for the second antibody immobilized in the barrier zone to bond to the labeled antigen Therefore, it is unclear why the device of Boehringer et al. would not function properly or fail to perform its intended function if the labeled antigen is already bound to the second antibody of the barrier zone, when the function of the barrier zone is to compete for binding to the immobilized antibody, and this would occur either way. (pp. 10-11).

This highlighted portion of the Office Action refers to a “competitive format” of Boehringer, et al. in which the labeling zone 14 contains a labeled antigen and the barrier zone 16a contains an antibody. (Col. 10, ll. 61-67 and Col. 11, ll. 3-6). Even in this embodiment, however, the barrier zone 16a fails to include an antigen containing an optically detectable substance that is complexed to the antibody prior to the application of a test sample to the device, as required by independent claim 14.

Nevertheless, it appears that the Office Action attempts to remedy this deficiency by alleging that the labeled antigen is bound to the antibody and thus reads on the present claims. However, this only occurs after application of the test sample. In fact, the barrier zone of Boehringer, et al. is designed to prevent a labeled species from migrating further along the matrix unless the analyte concentration exceeds a certain threshold. If the labeled antigen were complexed to the antibody within the barrier zone prior to application of the test sample, the intended function of the barrier zone would be completely circumvented. In any event, Applicants respectfully submit that the Office Action’s interpretation of the claims is completely contrary to the ordinary understanding of such terms in the art and also to the specification and teachings of the cited reference.

Applicants emphasize that the proper standard under § 103 is whether the claimed invention as a *whole* when viewing the teachings of the references *in their entirety*. In this case, the present claims are so substantially different from the references, when properly viewed in their entirety, that one of ordinary skill in the art would not have conceivably modified and/or combined the references as suggested in the Office Action.

It is thus believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. As a final note, Applicants respectfully request rejoinder of the withdrawn method claims 20-28 if the remaining claims are otherwise allowable.

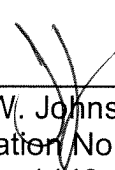
Examiner DiRamio is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Request.

Please charge any additional fees required by this Request to Deposit Account No. 04-1403.

Respectfully requested,

DORITY & MANNING, P.A.

11/6/08
Date



Jason W. Johnston
Registration No. 45,675
P.O. Box 1449
Greenville, SC 29602-1449
Telephone: (864) 271-1592
Facsimile: (864) 233-7342